

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

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STEPHANIE A. FISHER,  
MARK C. FISHER, and  
MARLENE L. FISHER,

**DECISION  
and  
ORDER**

v.  
Plaintiffs,

**07-CV-0347A(F)**

SMITHKLINE BEECHAM CORPORATION,  
doing business as GlaxoSmithKline,

Defendant.

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APPEARANCES: BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.  
Attorneys for Plaintiffs  
KATE E. GILLESPIE,  
FRANCES M. PHARES, and  
MICHAEL L. BAUM, of Counsel  
12100 Wilshire Boulevard  
Suite 950  
Los Angeles, California 90025

UNDERBERG & KESSLER, LLP  
Attorneys for Plaintiffs  
J. DAVIS SAMPSON, and  
R. SCOTT DeLUCA, of Counsel  
1900 Main Place Tower  
Buffalo, New York 14202

KING & SPALDING LLP  
Attorneys for Defendant  
ANDREW T. BAYMAN,  
S. SAMUEL GRIFFIN,  
ROBERT B. FRIEDMAN,  
FRANKLIN B. BRANNEN, JR., and  
HEATHER M. HOWARD, of Counsel  
1180 Peachtree Street  
Atlanta, Georgia 30309-3521

PHILLIPS LYTHE LLP  
Attorneys for Defendants  
PETER D. BRAUN, and  
ROBERT E. GLANVILLE, of Counsel  
Suite 3400  
One HSBC Center  
Buffalo, New York 14203-2887

**JURISDICTION**

This case was referred to the undersigned by Honorable Richard J. Arcara on June 18, 2007, for all pretrial matters. The matter is presently before the court on Plaintiffs' motions for sanctions (Doc. No. 79), filed December 21, 2007, and to conditionally seal certain documents filed in opposition to summary judgment (Doc. No. 87), filed December 28, 2007 ("Plaintiffs' Motions").

**BACKGROUND and FACTS**

On July 10, 2006, Plaintiffs Stephanie Fisher ("Fisher"), and her parents Mark C. Fisher ("Mr. Fisher"), and Marlene L. Fisher ("Mrs. Fisher") (together, "Plaintiffs"), residents of Jamestown, New York, commenced this action in United States District Court, Eastern District of Pennsylvania, alleging that while taking Paxil, an antidepressant drug manufactured by Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("Defendant" or "GSK"), a Pennsylvania corporation, Fisher, then 17 years of age, unsuccessfully attempted suicide by cutting her wrists. According to Plaintiffs, GSK, despite knowledge of an associated increased risk of suicidality in pediatric patients who took Paxil, failed to warn physicians, the medical community or the public of such risk. Plaintiffs assert six claims for relief including

negligence, Complaint ¶¶ 37-42 (First Cause of Action), negligent pharmaco-vigilance, Complaint ¶¶ 43-47 (Second Cause of Action), strict liability, Complaint ¶¶ 48-58 (Third Cause of Action), breach of express warranty, Complaint ¶¶ 59-65 (Fourth Cause of Action), fraud, Complaint ¶¶ 66-77 (Fifth Cause of Action), all asserted on behalf of Fisher, and a derivative claim asserted on behalf of Mr. and Mrs. Fisher for loss of consortium and loss on income, Complaint ¶¶ 78-79 (Sixth Cause of Action).

Defendant's answer was filed on September 5, 2006. On October 13, 2006, Defendant GSK moved to transfer venue to this district based on inconvenient forum and, by order filed April 25, 2007, the motion was granted.

Pursuant to Fed. R. Civ. P. 16(b), and Local Rule of Civil Procedure 16.1(a), a scheduling conference was conducted before the undersigned on August 29, 2007. Based on the parties' presentations at the scheduling conference, on August 30, 2007, the court issued a Scheduling Order, filed September 5, 2007 (Doc. No. 58) ("August 30, 2007 Scheduling Order"), stating, in pertinent part, that "[i]n accordance with Section 2.1A of the Plan for Alternative Dispute Resolution, this case has been referred to mediation," August 30 2007 Scheduling Order ¶ 1, and establishing September 13, 2007 as the deadline for filing any motions to opt out of the court's Plan for Alternative Dispute Resolution ("ADR Plan"). *Id.* ¶ 2. The August 30, 2007 Scheduling Order further provides that "[c]ounsel's attention is directed to Fed. R. Civ. P. 16(f) calling for sanctions in the event of failure to comply with any direction of this court." *Id.* ¶ 8.

Pursuant to the ADR Plan and August 30, 2007 Scheduling Order, mediation between the parties was scheduled for November 28, 2007, in Buffalo, New York, with Michael Brady, Esq. ("Brady"), acting as mediator pursuant to a Stipulation, both

executed by counsel for Plaintiffs and Defendant, as required by the ADR Plan and filed on September 20, 2007 (Doc. No. 61) (“mediation stipulation”). Plaintiffs’ counsel, Frances M. Phares, Esq. (“Phares”), requested permission to file a legal memorandum in excess of the normal ten pages, which Brady granted and, on November 21, 2007, Plaintiffs’ attorneys delivered to Brady a mediation binder containing an 18-page legal memorandum and 27 exhibits.

On November 27, 2007, Defendant filed a motion for summary judgment (Doc. No. 72) (“Defendant’s Summary Judgment Motion”). Also on November 27, 2007, Phares, in accordance with the mediation stipulation, flew from New Orleans, Louisiana, where her law office is located, to Buffalo to participate in the scheduled mediation. On November 28, 2007, Plaintiffs drove from their home in Jamestown, New York to Buffalo to participate in the scheduled mediation, which required Mr. and Mrs. Fisher to close, for the day, the family restaurant they operate, and Fisher, a college student, to reschedule a biochemistry examination. Phares, Plaintiffs and Defense counsel Franklin B. Brannen, Esq. (“Brannen”), appeared as scheduled for the mediation session and GSK representative Ellen Hurdock, Esq. (“Hurdock”), appeared by telephone.

After Brady presented opening remarks regarding the general nature and purpose of mediation, Phares presented Plaintiffs’ case. Brannen then presented Defendant’s case, which consisted of handing Phares a copy of the memorandum of law in support of the summary judgment motion GSK filed the day before. Brannen also commented that Phares was likely traveling en route to Buffalo when Defendant’s summary judgment motion was filed and, thus, would not have been aware of the motion. Brady then requested to meet in separate “caucus” sessions with the parties

and, after meeting with Brennan, Brady informed Phares that Brannen had advised Brady that unless Phares could satisfactorily explain to Brannen why Plaintiffs' action was not time-barred by the applicable statute of limitations, Brannen was unwilling to settle for more than \$ 1,000, and was also unwilling to engage in further mediation, and the mediation session was terminated.

On December 21, 2007, Plaintiffs filed a motion (Doc. No. 79) ("Plaintiffs' Sanctions Motion") seeking sanctions pursuant to Fed. R. Civ. P. 16(f) and the ADR Plan based on Defendant's filing its summary judgment motion the day before the mediation session scheduled for November 28, 2007 and Defendant's unwillingness to participate in the mediation session in good faith. Plaintiffs' Sanctions Motion is supported by the Declaration of Frances M. Phares, Esq. (Doc. No. 80) ("Phares Declaration"), and the Affidavit of R. Scott DeLuca, Esq. in Support of Plaintiffs' Motion for Sanctions (Doc. No. 81) ("DeLuca Affidavit").

On December 28, 2007, Plaintiffs filed a motion (Doc. No. 87) seeking to conditionally seal certain documents filed that same day in opposition to Defendant's motion for summary judgment ("Plaintiffs' Sealing Motion"), attached to which is a legal memorandum in support ("Plaintiffs' Memorandum"). According to Plaintiffs, they request to have filed under seal those documents and exhibits filed in opposition to summary judgment which Defendant maintains are confidential as a courtesy to Defendant in order to afford Defendant an opportunity to meet its burden of establishing why such documents should be filed under seal.

In opposition to Plaintiffs' Sanctions Motion, Defendant filed on January 22, 2008, Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline's Opposition to

Plaintiffs' Motion for Sanctions (Doc. No. 93) ("Defendant's Response to Sanctions Motion"), attached to which are exhibits 1 and 2 ("Defendant's Exh(s). \_\_"), and the Affidavit of Franklin P. Brannen, Jr., in Support of SmithKlineBeecham Corporation d/b/a GlaxoSmithKline's Opposition to Plaintiffs' Motion for Sanctions (Doc. No. 94) ("Brannen Affidavit"). Also filed by Defendant on January 22, 2008 is Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline's Response to Plaintiffs' Motion to Conditionally File Documents and Exhibits Under Seal (Doc. No. 95) ("Defendant's Response to Sealing Motion"), attached to which are exhibits A through G ("Defendant's Exh(s). \_\_").

On January 29, 2008, Plaintiffs filed Plaintiffs' Reply Memorandum of Law in Further Support of Motion for Sanctions (Doc. No. 97) ("Plaintiffs' Sanctions Motion Reply"). Also filed on January 29, 2008, is Plaintiffs' Reply to Defendant GSK's Response to Motion to Conditionally File Under Seal Documents and Exhibits in Support of Plaintiffs' Opposition to GSK's Motion for Summary Judgment (Doc. No. 98) ("Plaintiffs' Sealing Motion Reply"), attached to which are exhibits 1 through 18 ("Plaintiffs' Exh(s). \_\_"). Oral argument on Plaintiffs' motions was deemed unnecessary.

Based on the following, Plaintiffs' Sanctions Motions is GRANTED; Plaintiffs' Sealing Motion is DENIED.

## DISCUSSION

### **1. Sanctions Motion**

Plaintiffs' Sanctions Motion seeks an award of attorney's fees and costs incurred

in connection with preparing for, travel to and from, and participating in the abbreviated November 28, 2007 mediation session in Buffalo. According to Plaintiffs, Brannen, acting on Defendant's behalf, demonstrated bad faith by failing to advise Plaintiff, prior to filing Defendant's summary judgment motion after Phares had commenced her trip to Buffalo, that Defendants were unwilling to fully participate in the mediation session, but that Defendant's participation was limited to offering \$ 1,000 to settle the matter, until and unless Plaintiffs first demonstrated why their claims are not time-barred under the applicable statute of limitations as asserted by Defendant's Summary Judgment Motion. Phares Declaration ¶¶ 12-16; DeLuca Affidavit ¶¶ 11-13. Defendant argues in opposition that (1) the motion is procedurally without basis because when Plaintiffs filed the Sanctions Motion, the ADR Plan rules permitted only a mediator to report any alleged improper mediation conduct, which Brady, the mediator, did not do, Defendant's Response to Sanctions Motion at 2-3; (2) the Sanctions Motion violates the confidentiality of the mediation process insofar as Plaintiffs, by filing the motion, have revealed communications made in connection with or during mediation sessions, *id.* at 3; and (3) Plaintiffs have misrepresented Brannen's good faith conduct in connection with the mediation setting in a futile attempt to cause Defendant to appear to have acted in bad faith by asserting that the initial \$ 1,000 settlement offer was presented as a "take-it-or-leave-it" offer, failing to make a counteroffer, insinuating that GSK's representative appeared at the mediation session by telephone because GSK did not take the mediation proceeding seriously, and claiming that Defendant waited until Phares was in route to Buffalo before filing for summary judgment, claiming not to have known of the statute of limitations defense asserted as the basis for summary judgment,

and maintaining that Defendant should have opted out of mediation. Defendant's Response to Sanctions Motion at 2-6. Defendant does not contest the authority of the court to establish the ADR Plan nor its power to sanction violations of the Plan. In further support of sanctions, Plaintiffs argue the ADR Plan does not prohibit a party from reporting mediation violations, Plaintiffs provided only the bare minimum information necessary to demonstrate Defendant's alleged violation of the ADR Plan and no confidential information, and that Defendant should have advised Plaintiffs that Defendant intended to file the summary judgment motion to allow Plaintiffs a reasonable opportunity to request an adjournment of the scheduled mediation session until after the summary judgment motion was decided. Plaintiffs' Sanctions Motion Reply at 2-4. A review of the record establishes Plaintiffs are entitled to sanctions based on Defendant's failure to participate in good faith in mediation.

First, there is no merit to Defendant's argument, Defendant's Response to Sanctions Motion at 2-3, that Plaintiffs' Sanctions Motion is without any procedural basis. Such argument is premised on a previous version of the ADR Plan which provided only for a mediator, rather than a party, to report to the District Judge assigned to the case a party's failure to participate in good faith in the ADR process, whereas the ADR Plan was amended as of January 1, 2008 to permit either the mediator or any party to notify the court of alleged ADR Plan violations. *Id.* at 2 & n. 2 (citing ADR Plan § 2.3A). Defendant thus maintains that Plaintiffs are without any procedural basis for bringing the Sanctions Motion.

Although the version of ADR Plan § 2.3A in effect when Plaintiffs' Sanctions Motion was filed did not specifically provide for a party to report on another party's

failure to participate in good faith in the ADR process, neither was such action precluded. Moreover, Plaintiffs' Sanctions Motion is supported by the district court's "inherent power" to award attorneys' fees against the offending party and his attorney when it determines a party has 'acted in bad faith, vexatiously, wantonly, or for oppressive reasons.'" *Agee v. Paramount Communications Inc.*, 114 F.3d 395, 398 (2d Cir. 1997) (quoting *Sierra Club v. U.S. Army Corps of Engineers*, 776 F.2d 383, 390 (2d Cir. 1985)). Similarly, 28 U.S.C. § 1927, provides that

Any attorney or other person admitted to conduct cases in any court of the United States or any Territory thereof who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct.

28 U.S.C. § 1927 (italics added).

Additionally, the August 30, 2007 Scheduling Order provided that this case had been referred for mediation, August 30, 2007 Scheduling Order ¶ 1, that any party desiring to opt out of mediation was to file a motion to do so by September 13, 2007, *id.* ¶ 2, and directing the parties' attention "to Fed. R. Civ. P. 16(f) calling for sanctions in the event of failure to comply with any direction of this court." *Id.* ¶ 8. Moreover, this court's ADR Plan specifically provides that "[a]ll parties and counsel shall participate in mediation in good faith. Failure to do so shall be sanctionable by the court." ADR Plan § 5.8G. Accordingly, the court is authorized to sanction Defendant if Plaintiffs properly demonstrate that Defendant failed to participate in the November 28, 2007 mediation session in good faith and, as such, Plaintiffs' Sanctions Motion is not without any procedural basis.

Defendant argues that in bringing the Sanctions Motion, Plaintiffs revealed

confidential information in violation of the ADR Plan. Defendant's Response to Sanctions Motion at 3. Defendant specifically objects to Plaintiffs' disclosure of Defendant's \$1,000 settlement offer. *Id.* In opposition, Plaintiffs assert they did not disclose any confidential information in support of the Sanctions Motion but, rather, provided only "what was absolutely necessary for reporting that Defendant violated the ADR Plan." Plaintiffs' Sanctions Motion Reply at 3.

This court's ADR Plan also provides that "[m]ediation is confidential and private," such that no mediation participant may communicate any confidential information acquired during mediation without the consent of the disclosing party, including "[a]ll written and oral communications made in connection with or during the mediation session, any positions taken and any views of the merits of the case formed by any participant, including parties, counsel and the Mediator. . . ." ADR Plan § 5.10A.1. Nevertheless, the confidentiality of information disclosed during mediation will not prohibit "a participant from making such disclosures as are required by law." ADR Plan § 5.10A.4(f). In the instant case, the record establishes that Plaintiffs disclosed only the most minimal information necessary to establish that Defendant's conduct is sanctionable.

In particular, although attorneys have been sanctioned for intentionally disclosing to the court settlement offers made during mediation proceedings, see *Bernard v. Galen Group, Inc.*, 901 F. Supp. 778, 782-84 (S.D.N.Y. 1995) (plaintiffs' attorney sanctioned for disclosing terms of two settlement offers, including specific dollar amounts, made by defendants during mediation process), here, the only settlement offered disclosed by Plaintiffs is a \$ 1,000 offer which can best be described as a "token" offer, rather than

any indication by either Plaintiffs or Defendant of the actual monetary value of Plaintiffs' claims. Furthermore, such information is necessary to establish Defendant's conduct is sanctionable based on Defendant's alleged lack of good faith in attending the November 28, 2007 mediation session, knowing full-well that Defendant did not intend to engage in any mediation until and unless Plaintiffs first explained why Defendant's asserted statute of limitations defense did not bar this action, effectively forcing Plaintiffs to respond to the merits of Defendant's Summary Judgment Motion filed while Phares, Plaintiffs' lead attorney, was traveling to Buffalo for the mediation. Accordingly, Plaintiffs' disclosure of Defendant's \$ 1,000 settlement offer in support of the instant motion did not violate the ADR Plan.

Nor is there any merit to Defendant's assertion, Defendant's Response to Sanctions Motion at 3-6, that Plaintiffs have misrepresented Brannen's conduct in connection with the mediation session in a futile attempt to make it appear that Defendant has acted in bad faith. Defendant particularly objects to Plaintiffs' characterization of Defendant's initial \$ 1,000 settlement offer as made on a "take-it-or-leave-it" basis when Defendant placed no such condition on the offer to which Plaintiffs failed to respond, *id.* at 4, insinuating that GSK's representative appeared at the mediation session by telephone because GSK did not take the mediation proceeding seriously, *id.* at 5, and claiming that Defendant waited until Phares was en route to Buffalo before filing for summary judgment, that Plaintiff was unaware of the statute of limitations defense given that Defendant pleaded such affirmative defense in the answer, and maintaining that Defendant should have opted out of mediation. Defendant's Response to Sanctions Motion at 5-6. Plaintiffs argue that despite

Defendant's many assertions in opposition to sanctions, Defendant has not, and cannot, deny having filed a summary judgment motion on the eve of the mediation session, with the knowledge that Phares was then likely en route to Buffalo, and without the courtesy of telephoning Phares and advising that Defendant was willing to offer only \$ 1,000 to settle the matter absent resolution of the statute of limitations issue, in time to permit the parties to seek an adjournment of the mediation session until after the summary judgment motion was decided. Plaintiffs' Sanctions Motion Reply at 3-4. Fairly considered, the record supports an award of sanctions against Defendant's attorney, Brannen, for failing to mediate in good faith.

In particular, as discussed, Discussion, *supra*, at 8, the district court has "inherent power" to award attorneys' fees against an offending party and such party's attorney upon determining the party "has 'acted in bad faith, vexatiously, wantonly, or for oppressive reasons,'" *Agee*, 114 F.3d at 398 (quoting *Sierra Club*, 776 F.2d at 390), as well as against an attorney under 28 U.S.C. § 1927. *Id.* A sanctions award under either basis of judicial authority requires "clear evidence" that the offending party's conduct was without merit and was undertaken for improper purposes. *Sierra Club*, 776 F.2d at 390 (inherent power); *Oliveri v. Thompson*, 803 F.2d 1265, 1273 (2d Cir. 1986) (28 U.S.C. § 1927). "Like an award made pursuant to the court's inherent power, an award under § 1927 is proper when the attorney's actions are so completely without merit as to require the conclusion that they must have been undertaken for some improper purpose such as delay." *Oliveri*, 803 F.2d at 1273. Nor is there any reason to await the final outcome of this matter before making a sanctions award against Defendant insofar as 28 U.S.C. § 1927 "does not distinguish between winners and losers, or between

plaintiffs and defendants. The statute is indifferent to the equities of a dispute and to the values advanced by the substantive law. It is concerned with only limiting the abuse of court process.” *Oliveri*, 803 F.2d at 1273 (quoting *Roadway Express v. Piper*, 447 U.S. 752, 759-64 (1980)).

Here, regardless of whether Plaintiffs misinterpreted Defendant’s initial \$ 1,000 settlement offer as made on a “take-it-or-leave-it” basis, Defendant does not deny having filed a summary judgment motion based on an affirmative statute of limitations defense the day before the mediation session after Phares had left her New Orleans office and boarded a flight to Buffalo a fact knowledge of which may be reasonably reported to Defendant’s attorney, and thus, vicariously, to Defendant. It is significant that Defendant does not deny that Brannen’s mediation session presentation was limited to presenting Phares with a copy of the memorandum of law supporting Defendants’ summary judgment motion, filed on November 27, 2007, and commenting, by long-distance telephone call, that Phares was likely traveling en route to Buffalo when Defendant’s summary judgment motion was filed and, thus, would not have been aware of the motion or the statute of limitations argument on which the summary judgment motion was based. Although Defendant raised expiration of the relevant limitations period as an affirmative defense in the answer, the asserted defense states, in its entirety, “[e]ach of the purported claims in Plaintiffs’ Complaint *may* be barred by the applicable statute of limitations or repose.” Answer (Doc. No. 31-10), Tenth Defense (Statute of Limitations) (italics added). Not only is such allegation equivocal, the statement also fails to provide any basis for the defense and, as such, is best characterized as ‘boilerplate,’ sufficient to preserve the defense for summary judgment

at trial, but insufficient to support Defendant's assertion in opposition to Plaintiffs' Sanctions Motion that Plaintiffs, upon attending the November 28, 2007 mediation session, should have been well-prepared to argue the issue.<sup>1</sup>

Even assuming, *arguendo*, that GSK representative attorney Ellen Hurdock ("Hurdock"), sought permission to participate in the mediation session by telephone for reasons other than a desire to avoid travel to participate in a likely unsuccessful mediation session, Defendant proffers no explanation as to why Defendant did not earlier advise Plaintiffs that it was filing a motion for summary judgment just before the scheduled mediation session, particularly given the fact that Defendant's counsel spent a fair amount of time preparing Defendant's Summary Judgment Motion is established by the numerous documents and exhibits filed in support of the motion. Nor does Defendant dispute that notifying Plaintiffs of the summary judgment motion in advance would have permitted Plaintiffs to request an adjournment of the mediation session and Phares to cancel her travel plans, thereby avoiding the need to prepare the mediation memorandum and saving Plaintiffs the cost of Phares's round-trip airfare from New Orleans to Buffalo, and a one-night hotel stay, as well as prevented Plaintiffs from losing the income necessitated by closing their family restaurant for the day, resulting in substantial savings to Plaintiffs. Furthermore, prior knowledge of Defendant's intention to file for summary judgment based on the statute of limitations defense would have

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<sup>1</sup> Although not raised by the parties, the court notes that absent from the record is any indication whether Defendant prepared and forwarded to Brady any mediation memorandum, as required by ADR Plan § 5.6 (requiring that "[n]o later than ten [10] days before the scheduled mediation session, each party shall submit to the Mediator a written 'Mediation Memorandum.'"), raising the statute of limitations issue, or whether, if prepared and forwarded to Brady, such argument, if included, was, with Defendant's required consent, ADR Plan § 5.7, even communicated to Plaintiff prior to the November 28, 2007 mediation session.

provided a basis for either Defendant or Plaintiffs to opt out of mediation that was likely to be unsuccessful given Defendant's position revealed for the first time at the mediation.

Accordingly, Defendant's failure to timely advise Plaintiffs of the summary judgment motion Defendant intended to file caused Plaintiffs to unnecessarily incur expenses for no good reason. Plaintiffs' Sanctions Motion is GRANTED as to Defendant and Brannen.

In the Phares Declaration submitted in support of Plaintiffs' Sanctions Motion, Phares provides a detailed accounting of the time expended preparing for the mediation session, including 19.8 hours to be billed for attorney preparation, Phares Declaration ¶ 20, 21.4 hours to be billed for attorney travel, *id.*, 4.5 hours to be billed for paralegal services, *id.* ¶ 20, and expenses consisting of shipping charges, airfare, hotel, taxi fares, mediator's services fee, parking and meals totaling \$ 1,320.63, *id.* ¶ 21. Phares, however, does not provide the hourly rate at which reimbursement is sought for attorney preparation, attorney travel, or paralegal services. Accordingly, Plaintiffs are directed to submit an affidavit providing such information **within 10 days of service** of this Decision and Order. Upon Plaintiffs' filing of such affidavits, Defendant and Brannen shall have **10 days** thereafter to file opposing affidavits.

## **2. Sealing Motion**

Plaintiffs' Sealing Motion seeks to conditionally file under seal certain exhibits in opposition to Defendant's summary judgment motion, explaining that such motion has been filed as a courtesy to Defendant and with regard to numerous documents

produced by Defendant in connection with this case which Defendant labeled “confidential,” in order to permit Defendant an opportunity to satisfy its burden of establishing that such documents should, indeed, be filed under sealed. Plaintiffs’ Memorandum at 1-2. Nevertheless, rather than presenting a legal basis for sealing the subject exhibits, Plaintiff argues that Defendant is unable to establish the requisite good cause for sealing asserting Defendant has improperly designated as confidential many documents containing Paxil’s safety and efficacy data, correspondence with the United States Food and Drug Administration (“FDA”), and deposition testimony. *Id.* at 2-4. According to Plaintiffs, because Paxil is now “off patent” - - *i.e.*, no longer patent protected,<sup>2</sup> and generic competition is allowed, such documents do not contain any legitimate trade secrets. *Id.* at 4.

The subject documents for which sealing is sought, *i.e.*, Dr. Glenmullen Declaration Exhs. A and B, and Gillespie Declaration Exhs. 7, 8 and 21, have not been electronically filed but, rather, were separately submitted to the court for *in camera* review in connection with Plaintiffs’ Sealing Motion, accompanied by the unfiled Affidavit of Kate Gillepsie, Esq. in Support of Plaintiffs’ Motion to Conditionally File Under Seal Documents and Exhibits in Support of Plaintiffs’ Opposition to GSK’s Motion for Summary Judgment (“Gillespie Affdiavit”). Gillespie provides a brief description of each of the documents for which conditional sealing is sought. In particular, Dr. Glenmullen Declaration Exh. A “is a true and correct copy of Dr. Glenmullen’s Report regarding

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<sup>2</sup> The term “off-patent” refers to a pharmaceutical product for which the patent has either been invalidated or, more commonly, expired. See *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1018 (N.D. Ill. 2003).

Paxil and the increase of risk of suicidality in adults, dated December 7, 2007.” Gillespie Affidavit ¶ 6. Dr. Glenmullen Declaration Exh. B “is a true and correct copy of Dr. Glenmullen’s Report regarding Paxil and the increased risk of suicidality and hostility in children and adults, dated December 7, 2007.” *Id.* ¶ 7. Gillespie Declaration Exh. 7 “is a true and correct copy of an excerpt from November 10, 1989, Paxil Integrated Summary of Safety.” *Id.* ¶ 3. Gillespie Declaration Exh. 8 “is a true and correct copy of a May 10, 1991 SmithKline Beechum letter with attached April 29, 1991 report on suicidal ideation and behavior.” *Id.* ¶ 4. Finally, Gillespie Declaration Exh. 21 “is a true and correct copy of a SmithKline Beecham internal memorandum entitled, Seroxat/Paxil Adolescent Depression: Position piece on the phase III clinical studies - CMAT Study, October 1998.” *Id.* ¶ 5.

Defendant specifically supports the Sealing Motion with regard certain pages 2-7, 9-18, 21-27, 29-32, 34-37, 39-46 and 50-58 of Exhibit A, and all pages of Exhibit B, of the Declaration of Joseph Glenmullen, M.D., filed on December 28, 2007 in opposition to summary judgment (Doc. No. 86) (“Dr. Glenmullen Declaration”), as well as Exhibits 7, 8 and 21 to the Declaration of Kate E. Gillespie, Esq., filed on December 28, 2007 in opposition to summary judgment (Doc. No. 83) (“Gillespie Declaration”). Defendant’s Response to Sealing Motion at 12. Defendant maintains such documents should be sealed because they contain sensitive and confidential commercial information, research, development information, and trade secrets regarding Defendant’s prescription pharmaceuticals Paxil and Paxil CR. *Id.* at 1. Defendant further maintains that the confidential information Plaintiffs seek to publicly disclose were previously tendered to Plaintiffs’ counsel in other litigation cases involving Plaintiffs’ counsel and

GSK and that Dr. Glenmullen's Expert Report Exh. A has been sealed in previous litigation. *Id.* at 2. According to Defendant, Plaintiffs are fully capable of utilizing GSK's confidential documents in this litigation without exposing such information to the public. *Id.* In reply, Plaintiffs assert Defendant has provided nothing more than broad generalizations and conclusory statement that fail to establish the requisite good cause to support sealing the subject documents. Plaintiffs' Sealing Motion Reply at 2.

The primary source of the documents Defendant maintains are confidential is the Paxil Investigational New Drug ("IND") and New Drug Applications ("NDA") files (together, "the NDA files"), located at GSK's facility in Philadelphia, Pennsylvania. Defendant's Response to Sealing Motion at 3. The NDA files contain comprehensive information regarding the development, manufacturing, packaging, labeling, marketing, and clinical experience pertaining to Paxil, as well as all correspondence between Defendant and the FDA relative to Paxil. *Id.* The NDA must provide data demonstrating to the FDA that the new drug is safe and effective for its intended uses. 21 U.S.C. § 355(b). Such safety and effectiveness must be demonstrated based on extensive material, data and information that must be submitted in an NDA. 21 C.F.R. § 314.50.

In the instant case, Defendant assets, and Plaintiffs do not dispute, that the IND includes detailed documentation describing Paxil's physical, chemical, pharmacological, and biological characteristics, method of preparation and assuring identity, strength, quality and purity, manufacturing process, prior toxicological and pharmacological data from pre-clinical testing, and any description of prior experience with Paxil in humans. Defendant's Response to Sealing Motion at 4. Adverse events concerning a drug,

whether experienced during clinical studies or after the drug is placed on the market, must be included in the NDA, which also includes periodic safety updates covering the entire period during which the drug is marketed. *Id.*

As relevant to the instant motion, Fed. R. Civ. P. 26 provides that “[t]he court may, *for good cause*, issue an order to protect a party or person from annoyance, embarrassment, oppression, or under burden or expense, including . . . requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specific way . . . .” Fed. R. Civ. P. 26(c)(1)(G) (italics added). Further, the FDA is required to “make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.” 21 C.F.R. § 20.20(a). Unless specifically exempt, all FDA records “shall be made available for public disclosure upon request regardless [of] whether any justification or need for such records have [sic] been shown.” 21 C.F.R. § 20.20(b).

Nevertheless, the public’s “common-law right of access” to judicial records is well recognized by the courts. *DiRussa v. Dean Witter Reynolds Inc.*, 121 F.3d 818, 826 (2d Cir. 1997) (citing *Nixon v. Warner Comm., Inc.*, 435 U.S. 589, 599 (1978); and *In re Orion Pictures Corp.*, 21 F.3d 24, 26 (2d Cir. 1994)). “The burden of demonstrating that a document submitted to a court should be sealed rests on the party seeking such action,” *id.* (citing cases), in this case, Defendant, the party claiming the subject documents are confidential. Furthermore, the FDA, recognizing that its records include

a plethora of confidential information which could be useful in products liability litigation and which courts may require disclosure of, has enacted 20 C.F.R. § 20.83 permitting the FDA to disclose such information in compliance with a final court order. Specifically, 20 C.F.R. § 20.86 permits disclosure of confidential information during FDA administrative proceedings or other court proceedings where such information is relevant and provided the FDA takes the necessary precautions to insure it discloses no more information than is necessary under the circumstances.

Although 21 C.F.R. § 20.61 considers as confidential and not subject to public disclosure information pertaining to trade secrets, and commercial and financial information, the court's review of the relevant documents in this case do not, on their face, contain trade secrets, commercial or financial information. Rather, the subject documents all relate to reports and data concerning the risk of suicidality in adults, children and adolescents using Paxil as compared to those using a placebo. Defendant has not attempted to explain how this information qualifies as trade secrets, or proprietary commercial or financial information. Nor do any of the documents contain information which, on its face, would provide the identity of any individual who either attempted or committed suicide. Rather, any such individual is identified only by a patient identification number and such broad characteristics as gender and race, that it is impossible to determine the true identity of each patient such that no further steps need be taken to insure disclosure of the documents reveals no more information than is necessary under the circumstances.

As for Defendant's argument that disclosure of the requested information will permit competitors to exploit such information so as to gain a competitive advantage in

the marketplace, Defendant's Response to Sealing Motion at 8-12, Plaintiffs maintain, and Defendant does not deny, that as Paxil has been on the market since 1992, it is no longer patent protected such that there is no safety or efficacy data regarding Paxil from which a competitor could possibly gain an unfair advantage. Plaintiffs' Sealing Motion Reply at 6. Indeed, the relevant regulations provide that a designation of exempt from disclosure under the Freedom of Information Act applied to any information submitted to the FDA and constituting a trade secret, commercial or financial information that is privileged and confidential in nature, "will expire 10 years after the records were submitted to the [FDA]." 21 C.F.R. § 20.61(d). In other words, any information Defendants submitted to the FDA more than ten years ago, Plaintiffs would be able to obtain through a Freedom of Information Act request.

Finally, insofar as Defendant maintains that the subject documents should be filed under seal because other federal courts have issued orders permitting similar or the same documents to be filed under seal in other litigation concerning Paxil, Defendant's Response to Sealing Motion at 4-5, Defendant fails to cite to any case, and the court's research has revealed none, supporting that assertion. Defendant has thus failed to meet its burden of establishing the requisite good cause to support sealing the subject documents.

Plaintiffs' motion to conditionally seal certain documents filed in opposition to summary judgment is DENIED.

## **CONCLUSION**

Based on the foregoing, Plaintiffs' Sanctions Motion, (Doc. No. 79), is

GRANTED; Plaintiffs' Sealing Motion, (Doc. No. 87), is DENIED.

Plaintiffs are ORDERED to file **within ten (10) days** of receipt of the Decision and Order an affidavit providing the hourly rates at which reimbursement is sought for attorney preparation, attorney travel, and paralegal services. Defendant shall have **ten (10) days** from service of such affidavit to file any response.

SO ORDERED.

*/s/ Leslie G. Foschio*

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LESLIE G. FOSCHIO  
UNITED STATES MAGISTRATE JUDGE

DATED: September 29, 2008  
Buffalo, New York